UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

THE J&J DEFENDANTS' PROPOSED
FINDINGS OF FACT AND CONCLUSIONS OF LAW

Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, L.P. (the "J&J Defendants") respectfully submit the following proposed findings of fact and conclusions of law regarding Procrit® and Remicade®.[1] The Track 1 Defendants' Common Proposed Findings of Fact and Conclusions of Law are incorporated herein by reference.

I. PROPOSED FINDINGS OF FACT RELATING TO PROCRIT®[2]

A. Erythropoietin

1. Erythropoietin ("EPO") is a natural human hormone that stimulates stem cells in the bone marrow to produce red blood cells. EPO is used to treat severe anemia, including anemia associated with complete or partial renal failure, anemia in AIDS patients receiving AZT therapy, anemia in cancer patients receiving chemotherapy, and anemia in patients undergoing surgery.

B. Procrit® and Epogen®

2. Ortho Biotech Products L.P. is a wholly-owned subsidiary of Johnson & Johnson. Ortho Biotech sells EPO in the United States under the brand name Procrit. Another company, Amgen, Inc., sells EPO under the brand name Epogen. Procrit and Epogen are exactly the same. They have identical FDA-approved labeling.

3. Ortho Biotech's right to sell EPO stems from a Product License Agreement ("PLA") with Amgen executed in 1985. The PLA gives Amgen the exclusive right to market EPO for anemia in dialysis patients. The PLA gives Ortho Biotech the exclusive right to market EPO for anemia in non-dialysis patients. Physicians, however, are not subject to the PLA and,

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[1] Because these findings and conclusions are being submitted before trial and before receipt of the testimony and exhibits, the J&J Defendants request leave to file additional proposed findings and conclusions after trial.

[2] Unless otherwise indicated, the proposed findings relating to Procrit are based on the anticipated testimony of William Pearson, Thomas Hiriak and/or Cathleen Dooley.

consequently, may lawfully administer either brand of EPO to any patients they choose.

C. Procrit's Delayed Entry Into the Market

4. Amgen began selling Epogen in June 1989. Ortho Biotech introduced Procrit in January 1991. Since Procrit and Epogen are identical, neither product has a safety or efficacy advantage compared to the other. When Procrit® was launched, physicians were already administering Amgen's product to non-dialysis patients. They had no medical reason to switch their patients to Procrit.

D. Ortho Biotech's Price Incentives

5. In May 1990, after Epogen was on the market but before Procrit was introduced, the Office of Technology Assessment for the United States Congress ("OTA") gave Congress a report entitled "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) (Defendants' Ex. 1046).

6. The OTA report lays out several different reimbursement options under both the ESRD program and under Medicare Part B. With respect to EPO administered under Part B, one of the available reimbursement options discussed in the report was to pay for it based on AWP. Congress was told that some Medicare Carriers were already using AWP "to derive an approved charge for physicians who administer [EPO] in their offices." Congress was also told that "[a]verage wholesale prices, however, are usually list prices instead of the transaction prices that providers actually pay for pharmaceuticals."

7. The OTA anticipated that Ortho Biotech's eventual entry into the market might result in discounted pricing. Specifically, the OTA predicted that Ortho Biotech would need to offer "price concessions and other benefits" in order to overcome Epogen's "brand loyalty" from being the "first brand on the market."

8. As the OTA predicted, when Procrit was launched in 1991, Ortho Biotech found

it necessary to offer targeted price incentives to physicians who treated anemia in non-dialysis patients, and to pharmacies that dispensed to non-dialysis patients. These price incentives were designed to overcome Epogen's accrued brand loyalty from being the first brand on the market.

9. Ortho Biotech first offered pharmacy rebates in August 1991, eight months after Procrit was launched. Ortho Biotech's pharmacy rebates varied between 4% off the list price and 10% off the list price. Ortho Biotech stopped paying retail pharmacy rebates in 1999.

10. Ortho Biotech's pharmacy rebates were widely advertised and promoted.

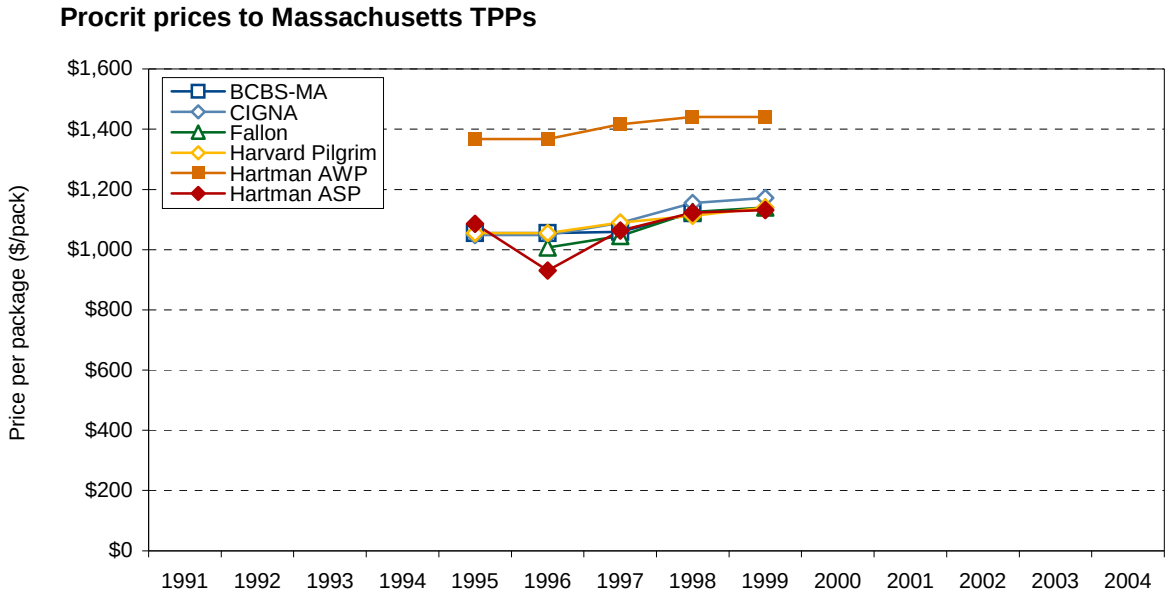
11. Ortho Biotech began offering rebates to physicians who treat non-dialysis patients in May 1991. Between 1991 and 1998, Ortho Biotech offered price incentives to physicians, in the form of rebates that varied between 5% and 12% off the list price. Starting in 1998 and continuing until 2001, Ortho Biotech offered physicians an across-the-board discount of 5% off the list price, which was administered as a chargeback.

12. Ortho Biotech's physician pricing incentives were widely advertised and promoted.

13. Ortho Biotech offered discounts on Procrit to other entities as well, including hospitals, Group Purchasing Organizations, health plans, and government agencies. Ortho Biotech gave modest discounts and administration fees to wholesalers and physician supply houses in exchange for prompt payment and for help in administering Ortho Biotech's physician incentive programs.

14. Blue Cross Blue Shield of Massachusetts, along with other Massachusetts health plans, directly benefited from the discounts on Procrit. The following chart compares the prices paid by BCBS/MA, Fallon Community Health Plans, Harvard Pilgrim Health Care, and CIGNA to the ASP and AWP figures reported by Dr. Hartman. All four companies purchased Procrit at

prices that closely tracked Dr. Hartman's ASPs.[3]



E. Competition from Aranesp®

15. In 2002, Amgen received regulatory approval to sell Aranesp® (darbepoetin alfa) for the treatment of chemotherapy-induced anemia, a market previously reserved to Ortho Biotech under the PLA. Aranesp, however, is not subject to the PLA. Consequently, Aranesp competes with Procrit in Ortho Biotech in the non-dialysis market.

16. When Aranesp was launched, its published AWP was 25% higher than its published list price. Because of this, whenever the dose-adjusted acquisition price of Aranesp and Procrit are the same, the provider who chooses to administer Aranesp receives higher net reimbursement compared to Procrit. From a reimbursement stand point, under an AWP-based system, Procrit is at a competitive disadvantage.

17. In an attempt to level the competitive playing field, Ortho Biotech lobbied

[3] Declaration of Eric M. Gaier, Ph.D. in Support of the Track 1 Defendants' Joint Motion for Summary Judgment (Mar. 15, 2006) at Fig. 4. *See also id.*, App. A at Figs. 16, 17, and 18; Decl. of Jessica V. Barnett in Support of the Reply Memo. of Law in Further Support of the Track 1 Defendants' Joint Motion for Summary Judgment (Apr. 28, 2006) at Ex. 6 (listing maximum and median spreads on Procrit purchases by Class 3 payors).

regional Medicare Carriers to adopt a Least Costly Alternative reimbursement policy with respect to the reimbursement of Procrit and Aranesp. Ortho Biotech argued that adoption of a Least Cost Alternative policy would reduce Medicare's reimbursement costs. One regional Medicare Carrier in Utah did adopt such a policy, but the policy was subsequently rescinded.

18. Due in part to Aranesp's potentially more attractive reimbursement rate, it was generally not in Ortho Biotech's self-interest to highlight the economic aspects of Procrit's reimbursement. Ortho Biotech therefore promoted Procrit as the less expensive product to the healthcare system, because payor reimbursement costs for Procrit are lower than for Aranesp.

F. Contracted Physician Discounts

19. In the face of direct competition from Aranesp, in 2001, Ortho Biotech began offering physicians the opportunity to enter into rebate contracts. These contracts provide rebate incentives based on the physician's purchase volume and were calculated as a percentage of the list price minus a standard 5% discount calculated off of the list price. From 2001 through 2003, the maximum rebate incentives, in addition to the standard 5% discount, were 1%, 3.75% and 11% for the three years, respectively.

20. Ortho Biotech reports its price incentives on Procrit to the Centers for Medicare & Medicaid Services in compliance with the Medicare Modernization Act. The discounts are reflected in the average selling price that Ortho Biotech reports to CMS, which CMS publishes on a quarterly basis.

G. Procrit's "Spread"

21. The published difference between Procrit's list price and AWP is 20%. However, because Ortho Biotech offered rebates and discounts to non-dialysis providers, the difference between Procrit's ASP (as defined and calculated by Dr. Hartman) and its AWP is more than 20%.

22. In his December 15, 2005 report, Dr. Hartman calculated spreads on 116 individual Procrit NDCs, and concluded that, between 1991 and 2003, 16 out of 116 Procrit NDCs had spreads between ASP and AWP that exceeded 30%.[4] However, Dr. Hartman's ASP and spread calculations are incorrect, because he failed to identify and comprehensively remove from his calculations all of the direct units sold to hospitals, managed care entities, and governmental entities. When these errors are corrected, only one Procrit NDC, in one year, had a "spread" in excess of 30%.[5]

23. Even using Dr. Hartman's uncorrected figures, however, when Procrit's spreads are calculated based on a weighted average of all Procrit NDCs, all but two of them are less than 30%, and the two that exceed 30% exceed it by a trivial amount -- 0.1% and 0.3%:

Weighted Ave. Procrit Spreads Calculated Per Dr. Hartman's Dec. 2005 Report						
1991	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**
22.7%	23.6%	25.1%	24.1%	27.3%	30.1%	27.8%
1998	**1999**	**2000**	**2001**	**2002**	**2003**	
29.4%	27.1%	25.6%	27.5%	26.7%	30.3%	

24. When the errors in Dr. Hartman's calculations are corrected, Procrit's weighted average spreads never exceeded 30%:[6]

[4] Dr. Hartman initially reported three anomalous spreads that were greater than 50%, including one that was 221.3%. Hartman Liability Report, Attachment G.4.c. These anomalous spreads do not appear in Dr. Hartman's Supplemental Report. *See* Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages ("Hartman Supplemental Report") dated February 3, 2006, Attachment G.4.c (Schau Decl., Exh. 9).

[5] Testimony of Jayson S. Dukes.

[6] Testimony of Jayson S. Dukes.

Weighted Ave. Procrit Spreads Calculated Per Dr. Hartman's Dec. 2005 Report (Corrected)						
1991	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**
23.0%	24.3%	24.4%	24.3%	23.2%	24.3%	22.3%
1998	**1999**	**2000**	**2001**	**2002**	**2003**	
24.5%	24.6%	25.1%	26.5%	25.7%	26.0%	

H. "Spread Competition"

25. Plaintiffs' contention that companies use spreads to "compete" with each other for market share is inapplicable to Procrit. Because of the market division in the PLA, Procrit and Epogen do not compete in the same market. Ortho Biotech has little incentive to secure sales in the dialysis market because it is required to compensate Amgen for sales of Procrit into Amgen's reserved market. Similarly, Amgen must compensate Ortho Biotech for sales of Epogen into Ortho Biotech's reserved market.

26. Plaintiffs have alleged that pharmaceutical companies, including Ortho Biotech, "inflate" their AWPs relative to competing drugs because providers are motivated to "sell and administer the drugs with the most inflated AWPs." This theory is also inapplicable to Procrit, because Medicare Carriers typically reimbursed EPO in dialysis at a fixed, statutory rate, and in non-dialysis on the lower AWP of either Procrit or Epogen.[7] Thus, Ortho Biotech had little incentive to raise Procrit's AWP above Epogen's AWP, as it would not have resulted a difference in the relative reimbursement amount under Medicare.

27. Ortho Biotech had little reason to market Procrit's spread after Aranesp was introduced, because Aranesp's reimbursement rate was more attractive. Consequently, it generally was not in Ortho Biotech's self-interest to highlight the economic aspects of

[7] When EPO is used for used for dialysis, Medicare's ESRD program reimburses providers at a fixed rate that is not based on AWP. *See* 42 U.S.C. § 1395rr(B)(11)(B).

administering Procrit. Ortho Biotech therefore promoted Procrit as the less expensive product to the healthcare system, because payor reimbursement costs for Procrit are lower than for Aranesp.

I. Procrit's Pricing Was Not Fraudulent

28. Ortho Biotech did not manipulate or inflate Procrit's AWP. Procrit's AWP was always 20% above its published list price.[8]

29. Ortho Biotech's reported list price was a bona fide price; the vast majority of Procrit's sales were made at the published list price, or within 10% of the list price.[9]

30. Ortho Biotech did not offer price incentives on Procrit in order to deceive payors. Ortho Biotech offered price incentives to encourage providers to dispense and administer Procrit to non-dialysis patients.

II. PROPOSED FINDINGS OF FACT RELATING TO REMICADE®[10]

A. Remicade®

31. Centocor, Inc. is a wholly-owned subsidiary of Johnson & Johnson. It was acquired by Johnson & Johnson in 1999. Before being acquired by Johnson & Johnson, Centocor was an independent company.

32. Centocor develops, manufactures and markets biotechnology-derived products, including Remicade (infliximab), a monocolonal antibody that blocks the immune system's production of tumor necrosis factor. Remicade is used to treat rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis.

33. Centocor launched Remicade in 1998. At its launch Remicade was approved for

[8] *See* Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Procrit, Admission No. 2.

[9] Testimony of Jayson S. Dukes

[10] Unless otherwise indicated, the proposed findings relating to Remicade are based on the testimony of Julie McHugh and/or John Hoffman.

the treatment of Crohn's disease. The FDA approved Remicade for the treatment of rheumatoid arthritis in November 1999. The indications for which Remicade is approved can be extremely debilitating.

B. Remicade's Pricing and Reimbursement

34. Remicade is administered to patients via intravenous infusion, which frequently takes place in a physician's office, but which may also take place in a hospital out-patient departments. An infusion of Remicade typically lasts about two and a half hours, including the time needed to prepare the patient for infusion, and the time needed to monitor the patient's condition after the infusion is completed.

35. Centocor did research with payors before deciding upon Remicade's initial launch price. The research showed that managed care organizations would be willing to reimburse physicians in the range of $1,300 to $1,700 per infusion. Since a typical infusion involves the administration of about three vials of Remicade, Centocor priced Remicade at launch at $450 per vial. This resulted in an average infusion cost -- for the drug alone -- of about $1,350, which was at the low end of the range payors were willing to pay.

36. Having never launched a product before, Centocor researched the meaning of AWP and learned that, for branded, self-administered products, AWP typically was 20% or 25% higher than the list price. Centocor also learned that, in the case of biological products, the difference between a therapy's discounted selling price and its AWP was usually more than 20% to 25%.

37. In general, physicians would have been unwilling to administer Remicade in an office setting if doing so would have caused them to lose money. Because Remicade was launched at a time when Medicare and most private payors were reimbursing physician-administered drugs at less than AWP, Centocor concluded that Remicade's AWP needed to be

higher than the physician's acquisition cost or physicians would have been unwilling to administer the drug in the office.

38. Centocor ultimately decided to recommend an AWP for Remicade that was 130% of the published list price. It believed that payors were likely to accept this figure as an appropriate reimbursement benchmark because it yielded a reimbursement amount for 3 vials that was within the range that payors indicated they were willing to pay. For example, a payor that reimbursed at 95% of AWP, such as Medicare, would end up paying about $1,667 per infusion (95% of $1,755).

39. Remicade's complete pricing history is set forth in the following table:

Time Period	Published List Price	Published AWP	AWP % Above List Price
Launch – June 18, 1999	$450.00	$585.00	30%
June 19, 1999 – Mar. 31, 2000	$470.25	$611.33	30%
Apr. 1, 2000 – Nov. 3, 2000	$493.29	$641.28	30%
Nov. 4, 2000 – June 6, 2001	$512.04	$665.65	30%
June 7, 2001 – Present	$532.00	$691.61	30%

40. During the class period, Centocor did not offer discounts, rebates, or other price incentives to physicians.[11] Accordingly, physicians likely could not acquire Remicade for much less than the published list price. Centocor did not offer discounts, rebates, or other price incentives to retail pharmacies.

41. Centocor offered pricing incentives to certain entities, such as health plans and managed care organizations, that reimburse the hospitals and physicians who administer Remicade. These price incentives reduce the payors' net reimbursement cost.

[11] *See* Plaintiffs' Supplemental Response to the J&J Defendants' Request for Admission and Interrogatories Concerning Remicade® ("Remicade Admissions"), Admission No. 4.

C. Remicade's "Spread"

42. Remicade's published WAC-to-AWP spread was 30%. Dr. Hartman contends that the spreads between Remicade's ASP and AWP were 30.8% to 36.1%:

Remicade Spreads Calculated Per Dr. Hartman's Dec. 2005 Report					
1998	**1999**	**2000**	**2001**	**2002**	**2003**
30.8%	33.4%	31.9%	36.1%	33.9%	34.3%

43. As with Dr. Hartman's Procrit calculations, however, these calculations are incorrect. During this time period, Centocor did not offer discounts to providers. Dr. Hartman's spreads exceed 30% only because he erroneously included certain government sales, the prompt pay incentive and the fees paid to specialty distributors for data and services, and the fees paid to Nova Factor and Priority Healthcare for their role in administering Centocor's Patient Assistance Program. When these and other errors are corrected, the spread on Remicade does not exceed 30%.[12]

D. Remicade's Pricing Was Not Fraudulent

44. Centocor did not manipulate or inflate Remicade's published AWP, which remained anchored at 130% to its published list price.[13]

45. Remicade's reported list price was a bona fide price; the vast majority of Remicade's sales were made at or about the list price.[14]

E. Centocor's Reimbursement Discussions

46. Plaintiffs contend that Centocor "marketed the spread" to physicians. Centocor engaged physicians in discussions relating to the practical aspects of infusion, including its financial implications. Centocor did so because rheumatologists were generally unfamiliar with

[12] Testimony of Jayson S. Dukes.

[13] Remicade Admissions, Admission No. 2.

[14] Testimony of Jayson S. Dukes.

the practice of purchasing and administering drugs in their offices, and would not have been willing to administer Remicade in their offices if it was not economically viable.

47. When Remicade was introduced, few, if any, rheumatologists had the capacity to infuse patients in their offices. The existing arthritis therapies were self-administered products that patients obtained at a retail pharmacy. Physician wrote prescriptions for these medications, but they were not involved in administering them to their patients.

48. In order to provide infusion services to their patients, many rheumatologists had to purchase infusion equipment, hire and train the personnel needed to administer infusions, acquire and set aside additional office space where the infusions could take place, and incur the other costs and risks associated with infusing patients in their offices.

49. In addition, the physician had to advance the money to purchase the drug, store the drug in a refrigerated unit until it was ready to be used, ascertain whether the patient is covered by insurance, and process and submit reimbursement claims to Medicare and private payors. Physicians might also need to obtain and pay for additional malpractice insurance.

50. A physician who was convinced that Remicade was medically appropriate can either administer Remicade in the office or send the patient to receive an infusion in a hospital setting. The cost to payors of reimbursing Remicade when it is administered in a hospital is significantly greater than the cost of reimbursing Remicade when it is administered in a physician's office. Centocor estimated that an infusion of Remicade in a physician's office costs payors $1,342, whereas an infusion in a hospital costs payors between $1,522 and $5,588.

51. In detailing Remicade to physicians, Centocor emphasized that in-office infusion was beneficial to patients, less costly to public and private payors, and a potential revenue source for the physicians themselves. Centocor made presentations to health plans designed to show

them the cost savings they could achieve if Remicade were administered in physician offices. Several health plans cooperated with Centocor to help persuade physicians that they should infuse Remicade themselves rather than send patients to the hospital. For example, Aetna worked with Centocor to identify physicians who are sending patients to hospital out-patient departments so that these doctors could be encouraged instead to administer Remicade in their offices.

52. Centocor gave physicians reimbursement-related information so that they would be able to determine whether providing in-office Remicade infusions would be financially viable given the individual characteristics of their practices. Centocor's Office-Based Infusion Guide, for example, lists five "benefits" of providing in-office infusions, including cost savings for payors, patient convenience, closer medical supervision of the infusion process, increased physician autonomy, and, potentially, "a financial benefit to a physician's practice."

53. Plaintiffs claim that providing physicians with information concerning the potential financial aspects of infusing Remicade is an unfair practice under Ch. 93A, and that the members of Classes 2 and 3 were somehow injured because this information was provided. In the case of Remicade, however, where the alternative to in-office infusion was to send the patient to the hospital, encouraging in-office administration saved payors the higher cost of reimbursing for treatments given in the hospital. Moreover, the reimbursement information Centocor provided to physicians was accurate.

54. Centocor's efforts to encourage in-office infusion were not conducted in secret. The Office-Based Infusion Guide, for example, was available for downloading and printing from Centocor's web site.

III. PROPOSED CONCLUSIONS OF LAW

1. Plaintiffs have not met their burden of proving that the J&J Defendants violated Ch. 93A, Mass. Gen. Laws Ann. ch. 93A, § 2(A) (West 2006), with respect to Procrit or Remicade.

2. Plaintiffs have not met their burden of proving that the J&J Defendants' pricing practices with respect to Procrit and Remicade were deceptive or unfair within the meaning of Ch. 93A. Among other things, Ch. 93A does not prohibit a pharmaceutical company from offering discounted pricing to health care providers, even if it means that the published AWP exceeds the average selling price by more than 30%.

3. In any event, Dr. Hartman's 30% liability theory lacks evidentiary support and is arbitrary and capricious as applied to Procrit and Remicade.[15]

4. Plaintiffs have not met their burden of proving that the J&J Defendants' marketing practices with respect to Procrit and Remicade were deceptive or unfair within the meaning of Ch. 93A. Among other things, Ch. 93A does not prohibit a pharmaceutical company from providing truthful information to health care providers concerning the cost of purchasing and administering physician-administered drugs and the reimbursement amounts applicable to those drugs.

5. Plaintiffs have not met their burden of proving that the conduct of the J&J Defendants was a proximate and "but for" cause of plaintiffs' alleged injuries. Among other things, plaintiffs did not prove that knowledge of the Procrit and Remicade spreads, as defined and determined by Dr. Hartman, would have caused payors not to use the published AWPs for

[15] Notably, Dr. Hartman originally testified that he thought payors expected spreads of 33%. *See* Decl. of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification (Sept. 3, 2004), ¶¶ 30(g) and 33(b).

Procrit and Remicade as a reimbursement benchmark.

6. All claims against the J&J Defendants that accrued prior to October 1997 are barred by the statute of limitations. Among other things, plaintiffs have not met their burden of proving that spreads of a magnitude similar to the spreads on Procrit and Remicade were inherently unknowable and incapable of detection through the exercise of reasonable diligence.

7. All claims against the J&J Defendants that accrued during the class period are barred by plaintiffs' failure to mitigate their alleged damages. Among other things, plaintiffs did not take steps to reduce the reimbursement allowance on Procrit and Remicade despite knowledge of spreads comparable to, and in many cases much greater than, the Procrit and Remicade spreads, as defined and determined by Dr. Hartman.

Dated: November 1, 2006

/s/ William F. Cavanaugh, Jr.

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Adeel A. Mangi
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000

Attorneys for the J&J Defendants

Certificate of Service

I certify that a true and correct copy of the foregoing was served on all parties on November 1, 2006 via LEXIS/NEXIS.

/s/ Andrew D. Schau
Andrew D. Schau